Celsion's OVATION 1 Study with GEN-1 in Ovarian Cancer Shows Strong Progression-Free Survival Treatment Effect Utilizing Medidata Synthetic Control Arm

Hazard Ratio of 0.53 for PFS in the Phase I Intent-To-Treat Population

Synthetic Randomization Provides Means to Evaluate Strategies to Accelerate GEN-1 Clinical Program for Newly Diagnosed Stage III/IV Ovarian Cancer

LAWRENCEVILLE, N.J. (March 26, 2020) – Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today jointly announced with Medidata, a Dassault Systèmes company, that examining matched patient data provided by Medidata in a synthetic control arm (SCA) with results from the Company's completed Phase Ib dose-escalating OVATION I Study with GEN-1 in Stage III/IV ovarian cancer patients showed positive results in progression-free survival (PFS). The hazard ratio (HR) was 0.53 in the intent-to-treat (ITT) group, showing strong signals of efficacy. GEN-1, designed using Celsion's proprietary TheraPlas platform technology, is an interleukin-12 (IL-12) DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein.

Celsion believes these data may warrant consideration of strategies to accelerate the clinical development program for GEN-1 in newly diagnosed, advanced ovarian cancer patients by the U.S. Food and Drug Administration (FDA). In its March 2019 discussion with Celsion, the FDA noted that preliminary findings from the Phase Ib OVATION I Study were exciting but lacked a control group to evaluate GEN-1's independent impact on impressive tumor response, surgical results and PFS. The Agency encouraged the Company to continue its GEN-1 development program and consult with FDA with new findings that may have a bearing on designations such as Fast Track and Breakthrough Therapy.

GEN-1's strong and encouraging treatment effect, evidenced by the synthetic control arm, suggests a potentially remarkable improvement in PFS, an FDA recognized surrogate for Overall Survival, and appears to confirm the science behind IL-12's ability to recruit the innate and adaptive elements of the immune system to fight malignancies. The strong PFS trend is

supported with previously published translational data that clearly demonstrates the pro-immune changes in the tumor micro-environment associated with loco-regional GEN-1 therapy.

Celsion's current randomized Phase II OVATION 2 Study in advanced ovarian cancer patients will commence in the 2nd half of 2020 and is designed to demonstrate a 33% improvement in PFS (HR=0.75) over current standard of care. PFS is the primary endpoint for this study.

Synthetic Control Arms have the potential to revolutionize clinical trials in certain oncology indications and some other diseases where a randomized control is not ethical or practical. SCAs are formed by carefully selecting control patients from historical clinical trials to match the demographic and disease characteristics of the patients treated with the new investigational product.

SCAs have been shown to mimic the results of traditional randomized controls so that the treatment effects of an investigational product can be visible by comparison to the SCA. SCAs can help advance the scientific validity of single arm trials, and in certain indications, reduce time and cost, and expose fewer patients to placebos or existing standard-of-care treatments that might not be effective for them. Medidata is in a unique position to create fit-for-purpose synthetic controls because of access to a pool of more than six million anonymized patients from nearly 20,000 previous clinical trials.

"Acorn AI, by Medidata, is proud to partner with Celsion to create a Synthetic Control Arm for this important clinical trial in advanced ovarian cancer patients with unmet medical needs," said Ruthie Davi, Ph.D., vice president, Data Science at Acorn AI, by Medidata. "This could have game-changing implications for patients, the medical community, and the industry. As demonstrated with the SCA for the OVATION I Study, we now have the opportunity to gain early scientific clarity to expedite the development of potentially life-saving treatments."

PFS data generated from this analysis comparing GEN-1 with SCA showed the following:

GEN-1 Population	**PFS Hazard Ratio (Confidence Interval)**
Intent-to-treat, n=15	0.53 (95% CI 0.16, 1.73); log-rank p=0.29
Per-protocol, n=14	0.33 (95% CI 0.08, 1.37); log-rank p=0.11

"The patients in the GEN-1 arm of the OVATION I Study virtually demonstrated a doubling of control of their cancer than the Synthetic Control Arm. Although these findings are not statistically significant due to the small numbers, they are impressive nonetheless," said Dr. Nicolas Borys, Celsion's chief medical officer. "This preliminary evidence of a strong treatment effect trend supports our commitment to the GEN-1 program, and we will aggressively explore means of accelerating its development with regulatory agencies and our investigators."

The Phase Ib OVATION I Study evaluated escalating doses of GEN-1 (36 mg/m2, 47 mg/m2, 61 mg/m2 and 79 mg/m2) administered intraperitoneally in combination with three cycles of neoadjuvant chemotherapy (NACT) prior to interval debulking surgery, followed by three cycles

of NACT in the treatment of newly diagnosed patients with Stage III/IV ovarian cancer. Previously reported data demonstrated median PFS of 21 months in the per-protocol population and 17.1 months in the intent-to-treat population for all dose cohorts, comparing favorably to historically reported median PFS of 12 months.

In the OVATION I Study, complete tumor resections (R0s) were achieved for all patients receiving the highest (79 mg/m2) dose of GEN-1, and approximately 86% of patients in OVATION I had a complete or partial response. All patients experienced a clinically significant decrease in their CA-125 protein levels as of their latest study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells. GEN-1 was well tolerated and no dose-limiting toxicities were detected. Intraperitoneal administration of GEN-1 was feasible with broad patient acceptance.

“We are extremely impressed with the high quality of the matched data from the Medidata SCA,” said Michael H. Tardugno, Celsion’s chairman, president and chief executive officer. “They were able to provide near-perfect matches for patient characteristics in our Phase Ib OVATION I Study. Based on this capability and the remarkable potential demonstrated by GEN-1, we plan to move forward with a partial synthetic control arm for the Phase II portion of our Phase I/II OVATION 2 Study with GEN-1 in advanced ovarian cancer. Using a SCA for a portion of the study will reduce costs and should improve the rate of enrollment as patients will be more likely to receive GEN-1 rather than placebo.”

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostic companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at www.medidata.com and follow us @Medidata , The Operating System for Life Sciences™.

About Acorn AI

Acorn AI, by Medidata, a Dassault Systèmes company, combines data, technology, and deep expertise to help life sciences companies deliver actionable insights across the entire continuum of clinical development. Acorn AI’s advanced analytics answers the most important questions in R&D and commercialization including accelerating breakthrough innovation, optimizing study execution and commercial success, and demonstrating the value of therapies. Built upon the Medidata platform comprising nearly 20,000 trials and more than six million patients, Acorn AI products feature the industry’s largest structured, standardized clinical trial

data repository connected with real world, translational, and other datasets. For more information, please visit www.medidata.com/acornai.

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About Celsion Corporation

Celsion is a fully integrated oncology company focused on developing a portfolio of innovative cancer treatments including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. For more information on Celsion, visit our website: http://www.celsion.com. (CLSN-G1 CLSN-OV)

Celsion wishes to inform readers that forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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